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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/656,630

09/05/2003

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EXAMINER

HOEKSTRA, JEFFREY GERBEN

ART UNIT

PAPER NUMBER

3736

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/656,630	Applicant(s) PARINS, DAVID J.	
	Examiner JEFFREY G. HOEKSTRA	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26, 28 and 33-46 is/are pending in the application.
- 4a) Of the above claim(s) 34-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) 2, 4, 17-26, 28 and 33 is/are allowed.
- 6) ☒ Claim(s) 1, 3, 5-9, 11 and 13-16 is/are rejected.
- 7) ☒ Claim(s) 10 and 12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>08/22/2008</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice of Amendment

1. In response to the amendment filed on 08/22/2008, amended claim(s) 1, 2, 4, 8, 9, 16, 17, 18, 20, 25, 26, and 28 and canceled claim(s) 27 and 29-32 is/are acknowledged. The current objections and rejections of the claim(s) is/are *withdrawn*. The following is/are set forth:

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 3, 5-7, 9, 11, and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tartacower et al. (US 5,606,981, hereinafter Tartacower) in view of Johansen et al. (WO 2004/091440 A2, hereinafter Johansen).

4. For claims 1 and 9, Tartacower discloses and shows an intracorporal medical device (as best seen in Figure 5), comprising:

- an elongate shaft (10) (column 8 lines 12-33) having a proximal end (the proximal end element 10) (as best seen on the left side in Figure 5) and an opposing distal end (the distal end element 10) (as best seen on the right side in Figure 5);
- a helically wound coil (50) (column 8 line 66 – column 9 line 47) having a plurality of windings (as best seen in Figure 5) forming a coil length (as best seen in Figure 5)

disposed about a portion of the distal end of the elongate shaft (column 8 lines 66-67) (as best seen in Figure 5);

- a thermoplastic polymer tube (81) (column 9 lines 39-47) including proximal and distal ends (as best seen in Figure 5) circumferentially disposed about a portion of the coil length (as best seen in Figure 5); and
- a plurality of discrete affixation points (located about elements 82 and 84, which are the proximal and distal ends of the thermoplastic polymer tube 81 attached to the coil 50) (column 9 lines 48-60) disposed along a portion of the coil length (as best seen in Figure 5), wherein each discrete affixation point fixes the thermoplastic polymer tube to two or more coil windings (as best seen in Figure 5), wherein each discrete affixation point is separated from other discrete affixation points by areas where the polymer tube is not affixed to the coil (column 9 line 61 – column 10 line 9) (as best seen in Figure 5).

5. For claims 3 and 11, Golds discloses and shows an intracorporeal medical device (as best seen in Figure 2), wherein the plurality of discrete affixation points forms a non-uniform pattern (the singular discrete affixation point of the tube to the multiple coil windings) along the coil length (as best seen in Figure 2).

6. For claims 5 and 13, Tartacower discloses and shows an intracorporeal medical device (as best seen in Figure 5), wherein the plurality of discrete affixation points forms a uniform pattern (the two discrete affixation points of the tube to the multiple coil windings) along the coil length (as best seen in Figure 5).

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7. For claims 6 and 14, Tartacower discloses and shows an intracorporal medical device (as best seen in Figure 5), wherein the discrete affixation point fixes 3 coil windings to the thermoplastic sleeve (as best seen in Figure 5).

8. For claims 7 and 15, Tartacower discloses and shows an intracorporal medical device (as best seen in Figure 5), wherein each discrete affixation point is a discrete element aligned orthogonal to the windings (as best seen in Figure 5).

9. Thus for claims 1, 3, 5-7, 9, 11, and 13-15, Tartacower discloses the claimed invention, as set forth and cited above, except for expressly disclosing (a) wherein at least some of the discrete affixation points are spaced from the proximal and distal ends and (b) wherein each of the affixation points is disposed about only a portion of the outer perimeter of the helically wound coil.

10. Johansen teaches an intracorporal medical device, comprising *inter alia*: a helically wound coil (20) (paragraphs 20-22) having a plurality of windings (24) forming a coil length (as best seen in Figure 2) and a plurality of discrete affixation points (22) (paragraphs 20-22) (as best seen in Figure 2) disposed along a portion of the coil length (as best seen in Figure 2), wherein (a) at least some of the discrete affixation points are spaced from the proximal and distal ends (paragraphs 20-22) (as best seen in Figure 2) and wherein (b) each of the affixation points is disposed about only a portion of the outer perimeter of the helically wound coil (paragraphs 20-22) (as best seen in Figure 2).

11. The claimed invention would have been obvious because the substitution of one known element for another would have yielded predictable results to one of ordinary

skill in the art at the time of the invention. Because both Tartacower and Johansen teach configurations of discrete affixation points along a portion of a helically wound coil length, it would have been obvious to one skilled in the art at the time of the invention to substitute one affixation configuration for the other to achieve the predictable results of configuring an intracorporeal medical device with alternate affixation configurations to control the flexibility of the intracorporeal medical device and affect its ability to traverse tortuous vasculature.

Claim Rejections - 35 USC § 103

12. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

13. Claims 8 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tartacower in view of Johansen. Tartacower teaches an intracorporal medical device, wherein each discrete affixation point has a length of 0.5 to 2 cm (column 9 lines 55-56). It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the size of the plurality of discrete affixation points along the length of an intracorporal medical device as taught by Tartacower in view of Johansen with a width of 0.1 to 0.5 mm and a length of 0.1 to 0.3 mm, because Applicant has not disclosed that a width of 0.1 to 0.5 mm and a length of 0.1 to 0.3 mm provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the size of the plurality of discrete affixation points along the length of

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an intracorporal medical device as taught by Tartacower in view of Johansen, because it provides a secure means for attaching a thermoplastic polymer tube to a plurality of coil windings (column 9 lines 39-60) and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Tartacower in view of Johansen. Therefore, it would have been an obvious matter of design choice to modify Tartacower in view of Johansen to obtain the invention as specified in the claim(s).

Allowable Subject Matter

14. Claims 2, 4, 17-26, 28, and 33 are allowed.
15. Claims 10 and 12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

16. Applicant's arguments with respect to claims 1, 3, 5-9, 11, and 13-16 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY G. HOEKSTRA whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J.H./

Jeff Hoekstra
Examiner, Art Unit 3736

/Max Hindenburg/

Supervisory Patent Examiner, Art Unit 3736